# HOSPITAL SURVEYS AND INCIDENT AND EVENTS REPORTING

# FINAL REPORT TO THE RHODE ISLAND GENERAL ASSEMBLY

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# EXECUTIVE SUMMARY

The Department of Health (HEALTH) received special funding in the amount of $300,000 in FY 2001 for the purposes of conducting a study of hospital care in the state. HEALTH has conducted hospital licensure surveys, reviewed the system of mandatory hospital reporting of patient care incidents and adverse events in light of the Institute of Medicine report on "medical errors", and studied the need for revisions in statutes, regulations and programs to assure quality hospital care.

HEALTH assembled a multi-disciplinary hospital survey team to conduct focused, on-site surveys of the fourteen licensed hospitals in the state. Because Medicare has "deemed" the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) as its primary certification agent, limiting support of state licensure agencies, Rhode Island has not had resources for hospital surveys over the past forty years. An Interim Report issued in March of 2001 incorporated the nine surveys that had been completed at that time. This Report includes the Department's final report on its survey findings for all of the fourteen (14) licensed hospitals. HEALTH also conducted a thorough review of the hospital incident and events reporting system, including an on-site review during each of the surveys. The New York State Department of Health, which has the most comprehensive incident review program in the US, provided consultative services.

**Findings:**

1. Hospitals in Rhode Island are under stress. Our discussions with hospital executives reveal:

- Difficulty in recruiting and retaining critical professional staff,
- Major shortcomings in the availability of an adequate supply and continuum of psychiatric services, especially for children and adolescents,
- An increasing administrative burden in admissions, utilization review and billing,
- Cash flow delays in claims payment,
- The challenge of caring for older, more frail patients with complex chronic diseases, and
- The tasks of meeting the needs of a more ethnically and linguistically diverse population.

2. Adverse patient care incidents are under-reported because there are different interpretations about what should be reported. The state has not been able to invest in training hospital staff on the reporting requirements. There has been no systematic review of incident reports by HEALTH.

The surveys revealed that the peer review processes of hospitals are weak: Of the fourteen (14) hospitals, five (5) were considered to be compliant; six (6), which were considered minimally compliant, provided evidence of some case reviews, but were lacking in one or more areas and were provided with cautionary feedback; and three (3) hospitals received deficiency citations for lack of peer review.

3. The number of patient complaints about hospital care has been rising. Complaints are often complex, and may involve hospitals, other health care facilities, and health professionals. It is important to note that the number of complaints that are substantiated upon investigation and result in citations of the hospital has remained stable for the last four years while there has been a 90% increase in the number of complaints.

4. Licensing regulations require that there be evidence that "medical, nursing and other services are provided under an integrated written plan of care for each patient." The integration of many elements of patient care is one of the most significant functions of a hospital. While four (4) hospitals were determined to be in compliance with care planning requirements, the Department cited five (5) hospitals for deficiencies with respect to inadequate development and/or use of care plans. In addition, five (5) hospitals were not cited for non-compliance with care planning, but cautionary feedback was provided to the hospitals' management at the exit conferences.

5. Two (2) hospitals were cited for demonstrated patterns of failure to conduct medical staff credentialing activities on a timely basis. At the remaining twelve (12) hospitals, lapses were determined to be minimal and no deficiencies were cited regarding medical staff reappointments at those hospitals. However, in reviewing credentialing files, surveyors were alerted to inadequate health screenings of medical staff. Ten (10) of fourteen (14) hospitals were determined to be deficient with regard to health screening requirements for physicians and other staff. Appropriate health screening for staff that has patient contact is an important element of infection control that requires more attention at these facilities.

6. The use of restraints is an important patient rights issue. Federal and state regulations require an assessment of the need for restraints, a selection of the least restrictive option for restraint, and a physician's order to use restraints. Two (2) hospitals received deficiencies for the use of restraints without a physician's order. Six (6) hospitals received cautionary feedback regarding the assessment process and the use of the least restrictive approach to restraint usage. Six (6) hospitals were determined be in compliance with these requirements.

7. Medication errors have been a major concern in patient safety studies. The surveyors identified 1,842 medication error reports, of which 104 were pharmacy errors. Most errors were detected before a patient received the medication. No deficiencies were cited, but the potential for patient harm was clearly identified.

8. Critical Care Unit management was assessed by evaluating the qualifications of the medical director of the unit and the responsibilities assigned to that physician. Several hospitals did not have written position descriptions for the medical director of the unit. The surveyors did provide informal cautionary advisories to several hospitals, but no deficiencies were cited.

9. Discharge planning has been a hospital system of considerable concern, particularly because patients are released from the hospital earlier in the course of care than in the past. Many discharged patients need early and intensive follow-up care, which is best arranged prior to release from the hospital. This aspect of patient care requires the same kind of integrated management as inpatient care planning. Some records reflected the initiation of discharge planning late in the hospital stay, and some records reflect a failure to identify post-discharge needs. Several hospitals received cautionary feedback regarding these findings. One hospital received discharge planning related deficiencies and this hospital will remain under review until full compliance is achieved.

10. Emergency Departments were generally in compliance with the regulations, but patient overload in the ED was identified as creating a risk of poor quality care and reduced access. A number of concerns were raised by ED medical and nursing staff that are important influences on the quality of care. Patients with mental health and substance abuse problems present major challenges for emergency departments, with more insurance hurdles to obtain inpatient admissions, fewer options for immediate follow-up after ED discharge, and very limited options for the care of adolescents and children. Managing the care of patients who are held in the emergency room until a bed becomes available is a second challenge. Limited inpatient bed availability backs up patients into the ED and diverts attention of the staff. The inability to admit patients to inpatient services results in diversion of EMS vehicles to other hospitals' emergency departments.

**RECOMMENDATIONS**:

1. Initiate a partnership with the hospitals, state agencies and insurers to address the issues of hospital emergency departments.

A. Facilitate discussion of improved management of intoxicated persons and persons in need of substance abuse treatment who present to emergency departments, in active partnership with DHS, MHRH, DCYF, insurers, and the treatment community.

B. Facilitate discussion of streamlined referral procedures, improve communication with community providers, and increase access to

outpatient resources for behavioral health clients presenting to emergency departments, in active partnership with MHRH, DHS, DCYF, insurers, and the treatment community.

C. Monitor emergency department waiting times, holding times and diversion status, working with the hospitals and the Hospital Association of Rhode Island (HARI) to improve care efficiency and effectiveness.

2. Facilitate improvements in the process of care to improve quality and satisfaction.

A. Initiate and sustain a program to control antibiotic-resistant infections, particularly Methacillin-resistant Staphylococcus Aureus and Vancomycin-resistant enterococcal infections in health care facilities and in the community.

B. Develop and implement strategies to improve medication management in cooperation with HARI, the hospitals and the School of Pharmacy at URI.

C. Work with public and private partners to improve quality.

3. Increase state oversight of hospitals.

A. Provide regulatory surveys of hospitals on an annual schedule, using Joint Commission survey reports, complaints, incident and events reports, and national trends to focus surveys on specific aspects of hospital care.

B. Clarify incident and event reporting definitions and reporting requirements. Use active survey methods to ascertain incidents and events, and provide regular reports to all hospitals on the types of incidents and events reported and the conditions that led to reportable situations. Incorporate incident and event reporting into the Health Care Quality Performance Measurement and Reporting Program (HCQP).

C. Make the findings of hospital surveys public through the department's web site and by other appropriate means.

D. Develop necessary resources for hospital licensure oversight activities.

INTRODUCTION

The provision of health care services, including hospital services and oversight may be considered from three perspectives: ***structure, process and outcome***.

**"Structure"** includes consideration of the adequacy of the organization and resources available to support the provision of services. Examples of structure from the "provision of care" perspective would include a governing board and management structure that oversees the hospital adequately, or a staff of professionals and support workers that provides adequate care to the hospital's patients.

**"Process"** includes providers' activities and behaviors in meeting the patients' needs and expectations. Examples of processes include development and implementation of infection control measures, discharge planning activities, and pre-operative work-ups, that include a recent history and physical examination.

**"Outcome"** is the resulting effects of the structure and the process of health services on the health of the patient. An example of an outcome is the improvement in health status of an open-heart surgery patient at discharge.

To assure the public that hospital services are being appropriately provided, each of these dimensions of hospital care provision must be considered. The hospital is responsible for providing quality health care services for all its patients. Traditional hospital licensure programs have focused primarily on assuring that the structure and process of care meet minimum standards. Consideration of outcome measures in traditional licensure oversight programs has largely been to investigate causes of specific instances of significant and readily observable poor outcomes and to require correction of deficiencies noted with regard to established structure and process standards. More recently, increased attention is being given to the regular measurement and public reporting of the health outcomes of hospital services provided to groups of patients in Rhode Island and elsewhere. Inter-hospital and inter-regional comparisons of hospitals' "health outcomes" are often utilized to assess the relative quality of care provided by a hospital or a group of hospitals. To a significant extent, the public reporting of health outcomes of hospital care is intended to provide the stimulus for hospitals to take "corrective actions" by evaluating the factors responsible for health outcomes that are not optimal and initiating actions to address such factors through "quality improvement" initiatives.

There must be a balance between the internal self-correcting structure, process and outcome assessments of the hospital and the external regulation of care by the licensure and certifying agencies. A key question for the hospital surveys undertaken by HEALTH this year is whether the balance needs to be shifted toward external regulation in order to promote the highest quality of hospital care.

The Statutory Charge to the Department of Health

The purpose of the Health Facilities Licensing Act (the "Act"-Chapter 23-17 of the Rhode Island General Laws) is "to provide for the development, establishment, and enforcement of standards:

(1) For the care and treatment of individuals in health care facilities;

(2) For the maintenance and operation of health care facilities which in the light of advancing knowledge, will promote appropriate access and safe and adequate treatment for individuals receiving health care facility services; and

(3) For the encouragement of quality improvement in all aspects of the operations of health care facilities."

The Health Facilities Licensing Act authorizes the Department to issue licenses to hospitals and other health care facilities provided that such entities meet and maintain minimal standards as established in statute and regulation. The Act also prohibits the conduct of health facility operation without licensure. The Department is directed to issue a license to an applicant "if the applicant and health care facility meet the requirements under this chapter (23-17) and such rules and regulations as may be established in accordance therewith." The Act also provides that each health facility license "shall expire by limitation on the thirty-first day of December following the issuance and may be renewed from year to year after inspection, report, approval and collection of fees by the licensing agency. The inspection shall be made any time prior to the date of expiration of the license."

Under the Act, the primary means for the Department to ascertain that an applicant is in compliance with facility licensure requirements is, as noted in the preceding paragraph, through annual inspection- that is, onsite review of records and activities to determine the extent to which the facility actually meets the specified regulatory requirements. In this regard, the Act authorizes the Director of Health to "make or cause to be made such inspections and investigations as it deems necessary including medical records." The Director of Health is authorized to enter and to inspect any and all records and operations of a licensed health care facility for the purposes set forth in the Act. Through the Act, the General Assembly has provided the Department of Health with significant responsibility, authority and jurisdiction to regulate the activities of health care facilities in Rhode Island through a licensure program.

Historically, the Department has not conducted annual relicensure inspections for hospitals. Primarily, this is a consequence of the absence of state appropriations for hospital surveys. Although hospitals arguably represent the most complex form of licensed health facility operations, the Department's onsite hospital inspection activities have been limited to the investigation of complaints and to the occasional conduct of a federally funded "validation" survey of a single hospital's compliance with Medicare requirements.

Medicare, the federal program that provides hospital and other health care coverage to the overwhelming majority of older Americans, requires that participating hospitals either be surveyed for compliance with the Medicare Conditions of Participation by federally funded surveyors or be accredited by the Joint Commission on Health Care Organizations (JCAHO.) Medicare has thus "deemed" accreditation by the JCAHO as equivalent to satisfying its Conditions of Participation. Not surprisingly, the overwhelming majority of hospitals that participate in Medicare do so via JCAHO accreditation status. At the same time that Medicare was being implemented, state and federal concern with the suspect quality of care in nursing homes – the bulk financed through the federal-state Medicaid Program – focused attention and resources in that venue. As a result, over time, state financed oversight of hospitals in Rhode Island and virtually all the other states was never provided with resources necessary to conduct regular licensure surveys.

As a practical alternative to conducting its own regular and comprehensive licensure inspections and surveys, the Department relied upon the accreditation program operated by the Joint Commission on Health Care Organizations (JCAHO). The JCAHO is a private organization whose corporate members include the American Hospital Association, the American College of Surgeons, the American Dental Association, and the American College of Physicians-American Society of Internal Medicine. Hospitals pay fees to the JCAHO to participate in the accreditation program. All hospitals in Rhode Island are required by regulation to maintain accreditation by the JCAHO and are surveyed by the JCAHO every three years on a scheduled basis. The Act requires hospitals to furnish the Department with copies of JCAHO survey documents and provides that such materials shall be public.

Like many states, Rhode Island has undertaken steps to provide increased public access to useful information regarding health services, including hospital care. Most notably, in 1998 the General Assembly enacted the "Health Care Quality Program Act", Chapter 23-17.17. This initiative will provide the public with measures of quality outcomes initially for hospitals and subsequently for other settings. While comparable outcomes measurement is expected to provide useful information for consumers and other purchasers of health services, such efforts do not obviate the need for active oversight and monitoring of licensed health care facilities.

Over the past several years, the Department has become increasingly concerned with the level of resources available to conduct appropriate regulatory oversight of licensed hospitals. The hospital system itself has come under rapidly increasing financial and operational stress. Medicare DRG payments, managed care restrictions and unbridled competition from other sectors of the health care provider system have affected hospitals' operations dramatically. The need for increased active state licensure oversight is also demonstrated by the rapidly increasing level of complaints about hospital services received by the Department. Further, the growing concern about the adequacy of nurse staffing in hospitals requires that the Department maintain the capacity to assess such issues in an objective fashion.

Absent appropriate minimal resources to conduct regular hospital surveys, the Department has been reliant upon the JCAHO to perform hospital surveys. However, the JCAHO accreditation program, while vital to the pursuit of quality by hospitals both in Rhode Island and nationally, is a less than satisfying substitute for the Department's own survey and inspection of the hospitals that the Department licenses. The JCAHO accreditation program is funded and, to a significant degree, controlled by the accredited entities. The JCAHO accreditation process typically requires a hospital to be surveyed only once every three years and on a known schedule as opposed to the annual inspection required by the Act. Further, JCAHO survey standards do not include consideration of all of the state or federal regulations nor do they include consideration of complaint investigations. In sum, the Department is not convinced that it is acceptable to continue to rely primarily on privately funded and operated accreditation programs for state licensure purposes.

FY 2001 Appropriations Act and Legislative Guidance

During the 2000 Session of the General Assembly, the House Committee on Finance reviewed the current state support for hospital licensure surveys and recommended "$300,000 to pay for a Hospital Care Consultant to review enforcement of standards to promote appropriate access and safe and adequate treatment for individuals receiving hospital services. The review will include but not be limited to surveys of licensed hospitals to assess regulatory compliance."

Additional guidance was provided to the Department regarding the General Assembly's direction in the use of these monies in correspondence from Representative Antonio Pires and Senator J. Michael Lenihan, Chairman of the House Finance Committee and Chairman of the Senate Finance Committee, respectively (See Appendix 1). Representative Pires and Senator Lenihan directed the Department to review hospitals' compliance with section 23-17-40 of the Act relative to mandatory reporting of incidents and events. Concern was expressed that hospitals are not reporting errors and may be ignoring the letter and spirit of the law. The Department was charged with determining compliance with section 23-17-40 and suggesting statutory amendments, if needed, to improve hospital reporting.

Implementation

In correspondence dated 16 August 2000, Patricia A. Nolan, M.D., M.P.H., Director of the Department of Health responded to Representative Pires and Senator Lenihan. Dr. Nolan described the Department's initial plans for implementing the activities funded via the FY 2001 Appropriations Act regarding hospital surveys. (See Appendix 2.) The Department planned a two-pronged approach. The first area of focus would be review of the hospital incident and events reporting as authorized by section 23-17-40 of the Act. The second area of focus would be the creation of a special on-site hospital survey team to review selected areas of each licensed hospital.

## HOSPITAL REPORTS: INCIDENTS AND EVENTS AND SAFE MEDICAL DEVICES

### History

Section 23-17-40 of the Health Facilities Licensing Act establishes requirements for hospitals to report certain "incidents" and "events" to the Department of Health.

This section of the Act was enacted by the General Assembly in 1994. Its passage came in response to the concerns raised when a hospital failed to notify the Department of a death of a patient whose cervical cancer was not detected as a consequence of substantial errors made by its pathologist in interpreting the results of Pap tests. The Department only belatedly learned of the errors at the hospital when the facility's malpractice insurer, frustrated with the failure of the hospital to accept the insurer's repeated recommendation that the matter be reported to the Director, directly advised the Department of the relevant facts. The Department of Health conducted an investigation into the matter. One aspect of the resulting joint federal and state investigation involved the review of a selected sample of Pap tests that had been classified as normal by the hospital's pathologist. Based on the findings of this sample, considerable concerns were raised regarding the accuracy and clinical appropriateness of previous test interpretations at the hospital. Ultimately, some 10,000 tests were re-examined and revised clinical results provided to physicians and their patients, where appropriate.

Departmental review of the Act and related regulations revealed that, despite the health implications of the errors, the hospital was under no explicit mandate to report this type of medical error. Responding to the perceived shortcoming in hospitals' reporting requirements, Public Laws 94-52 and 94-126 were enacted by the General Assembly to establish section 23-17-40 of the Act. These new statutory requirements require hospitals to report specified "events" and "incidents" to the Department within 24 hours and 72 hours, respectively, of becoming aware of such occurrences. The new requirements were based upon similar legislation that had been enacted in New York in 1985. In October of 1996 gave full effect to the 1994 Act by amending the Rules and Regulations for Licensing of Hospitals (R23-17-HOSP) to include mandatory reporting of incidents and events.

### Implementation

Under the current Regulations, "reportable events" are occurrences that, for the most part, may have implications on the operation of the overall facility. Specifically, the regulations define reportable events as including:

a) fire or internal disaster in the facility which disrupts the provision of patient care services or causes harm to patients or personnel;

b) poisoning involving patient(s) of the facility;

c) infection outbreak as may be defined by and in accordance with reference 21 [Note: this reference is to the regulations pertaining to the reporting of communicable diseases];

d) kidnapping;

e) elopements from inpatient psychiatric units and elopements by minors who are inpatients (reportable to the Department of Health at the time the local municipal police are informed);

f) strikes, official strike notices, or other personnel actions that may disrupt services;

g) disasters or other emergency situations external to the hospital environment which adversely affect facility operations; and

h) unscheduled termination of any health care service or utilities vital to the continued safe operation of the facility or to the health and safety of its patients and personnel. Restoration of utilities through use of emergency systems is not reportable.

The Regulations require that the Department receive notice of any such events within 24 hours of that information becoming known to the hospital. For cases involving kidnapping or elopement, additional regulatory requirements include peer review and follow up reporting as to outcomes and corrective actions taken, if appropriate. Hospitals are also required to notify the Department promptly of any pending or actual labor actions affecting patient services and must file a plan, acceptable to the Director, for continued operation of the facility or for suspension or termination of facility operations should the labor action take place.

In contradistinction, the Act and the Regulations define “reportable incidents” to be occurrences which result in the injury of one or more specific patients. The regulatory definition follows.

> ***"Reportable incidents"*** are those which result in patient injury as defined in a) though j) or which involve matters described in k) and l):
>
> a) brain injury;
>
> b) mental impairment;
>
> c) paraplegia;
>
> d) quadriplegia;

e) any paralysis;

f) loss of use of limb or organ;

g) serious unforeseen complication resulting in extended hospital stay;

h) birth injury;

i) impairment of sight or hearing;

j) surgery on the wrong patient;

k) subjecting a patient to a procedure not ordered or intended by the patient's attending physician, excluding procedures not requiring a physician's order, medication errors, and collection of specimen, for laboratory study, obtained by non-invasive means of routine phlebotomy; or

l) any other incident reported to the malpractice insurance carrier or self-insurance program.

Each hospital has established policies and procedures necessary to collect internal reports of defined incidents and events and to file required notices to the Department of Health. This responsibility is typically assigned to the hospital's risk management department. Once the hospital has a reasonable belief that a reportable incident or event has or may have occurred, it must file a report with the Department within the prescribed time frames. The reports are transmitted electronically to the Division of Facilities Regulation without the inclusion of patient identifiers. Each report is reviewed by a senior nurse supervisor following receipt. Triage of response is necessary and appropriate, given limited resources and competing priorities. Some reports necessitate immediate response, while some, based upon the information provided, are clearly non-urgent and may require no action by the Department.

Typically, reportable events are relatively rare, but well defined. Hospitals have expressed few concerns and had only limited questions regarding their obligation to report defined events. Further, the events reported through this system are not infrequently already known to the agency from other sources.

Relative to events, reportable incidents are more common and the definition of a reportable incident has engendered more concern and discussion about which incidents are, in fact, required to be reported to the Department by the regulations.

In addition to state mandated reports of "incidents" and "events", the Department also monitors hospital reports it receives pursuant to the provisions of the federal Safe Medical Device Act of 1990. This Act regulates the notification of the federal Food and Drug Administration (FDA) and the manufacturer in all incidents that contribute to serious injury, death or illness that may have been associated with the use of a medical device. An incident is any unintended or unexpected event that occurs during

or in connection with patient care. The law is designed to ensure the safety and effectiveness of medical devices through monitoring of reports.

Experience

Tables 1, 2 and 3 present statewide summaries of hospital reports of "Incidents", "Events," and notices required under the FDA administered "Safe Medical Devices" Act, respectively, for the 1994 through 2000 period. Chart 1 depicts the total statewide numbers of reported incidents for the same period. Chart 2 shows the statewide total number of reports received each year from 1994-2000 under the FDA "Safe Medical Devices" reporting system. Note that only statewide totals are reported as the facility specific information reported to the Department, by statute, cannot be disclosed publicly.

It is important to note that, although the statute included kidnappings and elopements in its definition of "events", they are listed in these reports as "incidents." In contrast to the requirements regarding "incidents", the statute does not require any follow-up reporting regarding "events." The Department notes that kidnappings and elopements involve individual patients, can present significant risk, and may result from a faulty practice on the part of the hospital or an individual provider. Hospital review of such incidents, with possible corrective actions, is, in the Department's view, warranted. For this reason, several years ago the Department amended the hospital licensure regulations to require that peer review be conducted and follow-up reports be submitted for all kidnappings and elopements. Thus, pursuant to the regulations, they are treated as "incidents", and therefore are listed here as such. "Complications resulting in extended stay" has been further broken down into "Falls" and "Other". The second portion of Table I lists those incidents that fell within the category "any other incident reported to the malpractice insurance carrier or self insurance program". These have been broken out into sub-categories that represent some common issues.

It is also important to note that the compilations of reported incidents, by category, have evolved somewhat over the years. As a consequence, there may be variations in how the reports were categorized, especially in some of the less well defined categories. Any analysis of the data must recognize such limitations. The Department has recently undertaken additional steps to assure consistent classification of hospital incident reports. For example, in the past, perforations during endoscopies may have been listed under "reported to malpractice carrier - Perforation/laceration during procedure" or under "Complication resulting in extended stay - other", depending on how the report was presented by the hospital and how it was viewed by the Department when received. Such report is now listed under "complication extending stay", rather than "reported to malpractice." The categorization of "events" is straightforward and closely reflects the statutory groupings (except for the above-mentioned kidnappings and elopements). The Safe Medical Devices report lists the numbers of reports received, with no attempt to categorize by type; these reports are not numerous and no patterns are discernable.

The Institute of Medicine (IOM) Report and "Medical Errors" in Rhode Island

In November of 1999 the prestigious Institute of Medicine published a report entitled "To Err is Human: Building a Safer Health System". The Report concluded that preventable medical mistakes in the nation's hospitals cause as many as 98,000 deaths per year with associated costs of $29 billion. Additional negative consequences include permanent disability, unnecessary suffering and loss of time from work. An (admittedly simplistic) extrapolation of the rates of medical errors to the number of hospital discharges in Rhode Island suggests that medical errors result in the unnecessary deaths of approximately 158 to 342 individuals hospitalized in Rhode Island each year. While subsequent critiques have raised doubts about the validity of the estimated numbers of medication error related deaths in hospitals, there is general agreement that the reduction of medical errors in the hospital setting is an important endeavor.

The principal recommendations of the IOM Report included:

- Creation of a Federal Center for Patient Safety that sets national goals for medical error rates and tracks progress toward meeting those goals.
- A national mandatory medical error reporting system to collect data on errors that result in serious harm or death to patients.
- Federal and state laws that encourage the creation of voluntary medical error reporting systems in all health care facilities.
- Legal protection of data and information on medical errors when used by professional peer review organizations to improve health care quality.
- More focus on patient safety by professional medical societies and health care licensing organizations.
- Increased attention to the safe use of drugs by the Food and Drug Administration.

While there have been critiques of the IOM Report's underlying methodology (and thus the Report's estimate of the size of the problem of medical errors), there is broad agreement that reducing medical errors is an important goal. The IOM Report captured the attention of national and state policymakers as well as that of the public. Existing error reduction initiatives were re-energized and additional efforts to quantify and reduce medical errors were conceived and initiated.

President Clinton appointed a Quality Interagency Task Force and directed it to prepare recommendations to implement patient safety proposals. Upon receipt of their recommendations, he proposed several initiatives including creation of a quality improvement center to develop national goals for reducing medical errors, requiring patient safety programs in all hospitals participating in Medicare and devising a state-run mandatory medical errors reporting system.

As noted above, since 1994 Rhode Island has had statutory requirements for the reporting of incidents and events that occur in hospitals. The reporting of such occurrences is viewed as one of the key components of a systematic approach to error reduction. To review the adequacy of Rhode Island's present error reporting system, the Department of Health was fortunate to be provided with assistance from the New York State Department of Health with the assistance of Dr. Antonia Novello, Commissioner of Health.

Frederick Heigel, Director of the Bureau of Hospital and Primary Care Services, and his associate, Ellen Flink, provided Rhode Island with consultative services. On 3 October 2000 the New York State consultants also conducted a presentation of the system used for medical error reporting of adverse events (including medical errors) in that state (the New York Patient Occurrence Report and Tracking System - "NYPORTS") for an audience of forty hospital, Department of Health staff and other individuals interested in medical error reduction efforts. The information provided regarding NYPORTS was most useful to Rhode Island as the NYPORTS' authorizing language served as the model for Rhode Island's 1994 Public Law. NYPORTS has been in existence for more than fifteen years and is regarded as the pre-eminent national model for mandatory state level medical error reporting systems. A more detailed description of NYPORTS is included as Appendix 3.

The General Assembly enacted the reporting requirements to assure that the Department of Health received adequate and timely notice of the occurrences of specified incidents and events. Reporting initiates regulatory oversight and assures that hospitals take appropriate corrective actions. The Department's surveys found evidence that, as far as may be determined from record review and interview, most reportable events and incidents are reported. These reports serve to guide and inform complaint investigations and hospital survey activities.

There has been substantial and growing interest in the role that such reporting systems can play in broad based quality improvement initiatives. Indeed, New York's NYPORTS, now incorporates cooperative quality improvement initiatives with the ongoing participation of hospitals. Reporting is intended to stimulate internal quality assurance activities at the hospital. The state collects and publishes performance indicators as a stimulus for prudent purchases by third parties and the public. The costs of analysis of these data, for the hospitals and for the New York Department of Health, are significant, and misinterpretation can be also costly.

## Incident and Events Reporting - Conclusions

Based upon its consultants' input, reviews of the literature, and the information gathered by Department of Health staff from several seminars and workshops, improvements in the utility of Rhode Island's present hospital incident and events reports must include appropriate consideration of the following:

1. Alignment of incident and events reporting with the health care quality system, complaint investigation, and licensure/certification activities.

   The Rhode Island Department of Health proposes to use individual hospital reports for licensure investigations, and to provide the public with aggregated information for all hospitals to allow the tracking of trends. As more experience in interpreting the incident and event reports is gained, it is envisioned that this data would be incorporated into the health care quality reporting system.

2. More explicit definition of terms and reporting requirements –

   The requirements for reporting specific occurrences under Rhode Island's present regulations are not clear. More appropriate definition of terms and reporting requirements and procedures are required. The Department intends to revise the regulations to clarify existing definitions and reporting requirements. The hospitals and health professionals would participate in the process, as in all our rulemaking.

3. Comparability –

   Rhode Island's statutory and regulatory reporting requirements, categorization and related definitions of "reportable events" and "reportable incidents" are unique. According to a recent fifty-state survey of reporting systems, there is no common or standardized definition of "medical error." Additional areas and issues that must be addressed with regard to a national system include: scope (i.e., limited to hospitals or a broader range of facilities), mandatory versus voluntary reporting, confidentiality of reports, and use of data/feed-back loops. With non-comparable reporting systems in the fifty states, opportunities for scale economies and interstate cooperation and comparison are stymied. There is considerable recognition among the fifty states and the federal government of the usefulness of a standardized national approach that builds upon state-level programs.

   The Department believes that federal action and financial support are necessary to achieve substantial progress in the reduction of medical errors.

4. Resources –

   The 1994 enactment of the hospital incident and events reporting requirements provided the Department with a new source of information that can increase the effectiveness and targeting of the State's limited resources for facility oversight. The Act, however, did not include any additional personnel or financial resources to the Department of Health for implementation. Without additional resources, the development, implementation and oversight of the hospital incident and event reporting system by the Department have been limited and difficult. Improvements to the system will also have cost implications for hospitals as well; hospitals will likely

require additional personnel and other resources to meet increased reporting requirements.

## III. COMPLAINT INVESTIGATIONS

The primary focus of hospital survey activity conducted by the Division of Facilities Regulation is the investigation of complaints. As reported in Section IV herein, the only scheduled surveys are "validation surveys" done at the request of the federal Center for Medicare and Medicaid Services (CMS) –formerly known as the Health Care Financing Administration (HCFA) - for Medicare purposes. In addition, some investigations of "incidents and events" (see section "The Statutory Charge to The Department of Health-Hospital reports: Incidents and Events" herein) are initiated when review of one or more hospital reports indicates cause for concern or a developing pattern of reportable incidents. As a result, it is the number of consumer/patient complaints received by the Department of Health from the public that establishes the workload for hospital investigations.

As Chart 3 indicates, the workload over the last ten years has increased almost ten fold. Until 1992 the average number of complaints received was less than 20 per year. In 2000 the Department received 206 complaints. Also depicted in Chart 3 are the numbers of substantiated complaints for each year in the 1994-2000 period. These are complaints that, upon investigation, the Department can substantiate by means of evidence sufficient to demonstrate the substance of the complaint was both a violation of regulation. Citations were issued in these instances. Investigation responsibility is assigned to a senior nursing administrator to assure that all cases are properly investigated to assess compliance for both state licensure and federal certification rules and guidelines. Complaint investigations are performed by survey staff who have been trained to do federal "validation surveys".

Typically, hospital complaints are complex and often require the investigator to research the medical issues at the core of the complaint. Hospital care involves many more service providers per patient than care provided in other facilities, such as nursing homes. A typical hospital patient receives health care services from several physicians, nurses and related technical staff, all of whom may have to be interviewed to conduct a proper investigation. The broader range of acute care services received yields more complex medical records to be reviewed. Research, scheduling and conducting interviews, and reviewing complex records consume more resources per complaint in hospitals than these activities do in any other facility type.

The frequency and general classification of complaints has helped the Department to determine which areas of the regulations were to be considered during the survey process as explained in Section IV.

Until recently there has never been permanently assigned hospital survey staff or staff assigned to investigate hospital complaints. When CMS mandates and funds a hospital validation survey, a team composed of administrative and survey staff is formed *ad hoc.*

In early 2000, two nursing FTE have been assigned to do hospital complaint investigations due to the increasing volume and complexity of the complaints filed with the Department. This FTE commitment came from staff that previously had been dedicated to investigating complaints in long-term care venues. The long-term care complaint staff had been so assigned, after considerable criticism of the Department by advocates and the legislature. The assignment of dedicated complaint staff was designed to eliminate the backlog of nursing facility complaints that existed in the mid 1990's.

## IV HOSPITAL SURVEY ACTIVITIES

A five-person team was formed with a Principal Nursing Care Evaluator (PNCE), the Public Health Nurse Consultant (PHNC), the Chief, Regulatory Compliance Section (Pharmacy) and two Nursing Care Evaluators. The PNCE and the PHNC are both federally trained and have been active participants in the development of state hospital licensing regulations. All had previous experience doing surveys in the hospital environment. Additional entry-level survey staff were recruited to replace staff assigned to the hospital survey effort.

Since the established team was small and the time was limited, the surveys had to be effective as well as efficient. To address these concerns, it was determined that the surveys should be limited in scope, with a focus on particular predetermined areas and brief enough such that the team would have ample time to secure good information, yet be able to survey all fourteen hospitals. There also had to be ample time built into the schedule for the new team to perform, at a minimal level to maintain operations, their routine duties in the office that could not be appropriately reassigned to other staff.

The Focus Areas are:

Care Planning
Incident and Event Reporting
IV Labeling
Countersigning of Telephone Orders
Medical Staff Reappointment and Health Screening
Quality Improvement/ Peer Review
Psychiatric Services
Restraint Usage
Pharmacy Services
Direction of Critical Care Units
Discharge Planning
Emergency Services

These focus areas include hospital activities heavily influenced by nurse staffing, areas where practices have been changing significantly, and areas particularly sensitive to the effects of managed care organization practices.

These areas were also chosen based on prior experience with hospital compliance with state, federal and Joint Commission for Accreditation of Health Care Organizations (JCAHO) standards and concerns from CMS, that were expressed during recent training programs. Information gathered from the investigations of complaints filed by consumers, a limited number of CMS validation surveys, and JCAHO publications on national trends were utilized.

A unique feature of this survey initiative was that there was time set aside for the hospital administration to have a plain and simple conversation with the surveyors about the issues confronting the hospitals today. There was a lot of positive feedback about these opportunities to "vent" frustrations and to talk about best practices. One of these sessions re-enforced concerns and helped launch the Methacillin Resistant Staphylococcus Aureous (MRSA) work group described in the "other initiatives section" of this report. A summary of these discussions is included herein.

The scheduled surveys started on the second of January 2001. If facilities had been recently visited for other purposes, they were scheduled last. A copy of the survey schedule is included as Appendix 4. The compression of the schedule forced the survey teams to work extended days for which the team members were compensated with compensatory time off. Further, the "manager" members also worked on some week-ends to keep current with their normal workload. Compensatory time off was also given for the weekend work. All compensatory time was calculated at one and one half times the actual hours worked. All surveys were completed by early September 2001.

The individual focus area findings are summarized below.

CARE PLANNING

Licensing regulations require that there be evidence that "medical, nursing and other services are provided under an integrated written plan of care for each patient."

This topic was included in the hospital onsite review because the Department had recently cited a hospital for lack of patient care plans, and was concerned that the deficiency in this key area might be systemic and be indicative of issues related to nurse staff. The development and use of care plans by hospitals and the communication of such plans to other health care providers through written documentation, is essential for the provision of consistent, integrated, and high quality care. Arguably, the need for adequate development and use of care plans is greater now than in prior years as a consequence of observed changes in staffing patterns in hospitals. The Department observes that hospital staff are under considerable pressures, often "floated" among different units and assignments, and augmented with outside agency personnel. These pressures limit some of the usual opportunities for maintaining the cohesiveness of staff on a given unit and the staff's capacity to communicate and interact on the patient's behalf that have historically been part of hospital care. Recognizing that hospital stays are shorter and thus the opportunities for addressing patient care related concerns are

necessarily fewer, it is increasingly vital that all staff function and interact at the highest level possible. Care planning is the keystone to this effort.

Findings: Hospitals need to focus increased resources and attention to the adequate development and the use of care plans. While four (4) hospitals were determined to be in compliance with care planning requirements, the Department cited five (5) hospitals for deficiencies with respect to inadequate development and/or use of care plans. In addition, five (5) hospitals were not cited for non-compliance with care planning, but cautionary feedback was provided to the hospitals' management at the exit conferences.

QUALITY IMPROVEMENT/PEER REVIEW

Hospitals are required by state regulation, federal regulation and JCAHO accreditation standards to conduct quality improvement activities. While there are substantial similarities in these requirements, there are several areas where different (but not inconsistent) standards are set. Whereas the JCAHO requirements emphasize data collection and trending, allowing comparisons of performance, in quality improvement activities, state requirements also include peer review of individual cases. Given the JCAHO emphasis and the observed tendency of practitioners to minimize or avoid peer review, the Department was concerned that compliance with state requirements in this area may be diminished. Accordingly, compliance with state quality assurance regulations was selected as a focus area for this survey.

State and federal regulations require that ALL medical and surgical services be evaluated for appropriateness in diagnosis and treatment. This means peer review of selected cases. Records must demonstrate this, and include case identification, focus of the review, findings, conclusions and actions taken (if any).

The Department's survey team validated the concern that hospitals are doing less peer review, and the peer review performed is not well documented. Recently, a validation survey at one hospital resulted in a deficiency for lack of peer review. Of the fourteen (14) hospitals, five (5) were considered to be compliant; six (6), which were considered minimally compliant, provided evidence of some case reviews, but were lacking in one or more areas and were provided with cautionary feedback; and three (3) hospitals received deficiency citations for lack of peer review.

Given the findings on survey, the Department proposes to amend the existing regulations to clarify the requirements. For example, the present regulations require that hospitals evaluate all medical and surgical services for appropriateness in diagnosis and treatment. The Department will consider amending this to specify that "Evaluation shall include peer review of individual cases. The hospital shall maintain records of peer reviews documenting the case reviewed, focus of each review, findings, conclusions, any action taken and any follow-up on action taken."

Findings: The Department cited three (3) hospitals for failure to evaluate services for appropriateness of diagnosis and treatment. Six (6) facilities surveyed were deemed to be

at least minimally compliant with Quality Improvement/Peer review requirements, but received some cautionary feedback. Five (5) hospitals were determined to be compliant.

INCIDENT/EVENT REPORTING

Department staff reviewed hospitals for their current compliance with statute and regulation, and to identify areas that might warrant statutory or regulatory change. It appears that hospitals are generally compliant with the reporting requirements of the law. Discrepancies exist, however, in how individual hospitals interpret some portions of the law and regulations. Following dialogue and on close reading, most of the interpretations can be justified. Clarification is therefore needed and regulatory revisions are planned.

One category of reportable incident that seems particularly vulnerable to diverse interpretations is " serious unforeseen complication resulting in extended hospital stay". Some hospitals will report deaths under this criterion, while others may take a more literal view of the phrase "extended hospital stay" and not report deaths resulting from "serious unforeseen complications." Some hospitals interpret "unforeseen" as meaning "there is NO known risk" and, since most medical treatments have some known risk, even if the risk is minute, these hospitals may report next to nothing. Other hospitals view "unforeseen" differently and report any serious complication that was not "probable and expected". Perforation during endoscopy is an example of a complication that is serious and extends hospital stay, but may or may not be reported, based on the hospital's interpretation of "unforeseen".

Another category of reportable incident that may result in different reporting patterns is "any other incident reported to malpractice insurance carrier or self insurance program". Although this appears straight-forward, and is to most hospitals, those hospitals that are self insured AND utilize the same hospital personnel to fill traditional hospital roles (e.g., risk manager) as well as function as insurer, may find it difficult knowing where to draw the line between the two roles. Again, the Department intends to amend its regulations to clarify these reporting requirements in order to achieve consistent reporting standards across all hospitals.

Another modification that survey staff suggested relates to psychiatric patients. Currently, only elopements from *inpatient* psychiatric units must be reported. During the on-site review, survey staff noted a case of a patient, depressed and suicidal, who eloped from the ER. The hospital had done enough of an evaluation to determine that the patient was suicidal, and called the police when he eloped. The hospital should be responsible for the protection of this patient and the regulations should be revised to include mandatory reporting of outpatient elopements in addition to inpatient elopements. It may be appropriate to limit reportable outpatient elopements to those patients who might reasonably be thought to be a possible danger to self or others.

Medication errors are tracked by all hospitals, but are not reportable under current regulations, unless they cause serious negative outcomes that trigger under one of the existing categories. As a practical matter, since the volume is significant, the Department

does not want to receive reports on ALL medication errors; however, the Department believes that those errors, associated with harm or significant risk should be reported. The Department is proposing that hospitals report all medication errors that necessitate some clinical intervention, other than monitoring.

The Department notes that the number of incidents reported for 2001 has increased somewhat from prior years. It is likely that this noted increase may be due to improved compliance with reporting requirements. That is, it is likely that the increased number of reports is a product of more complete reporting and that the observed increase does not reflect an actual increase in these types of incidents. The Department notes that in the first six (6) months of calendar year 2001, 147 reports have been submitted while in all of 2000, 158 reports were submitted. The Department believes this increase in reporting is a consequence of improved compliance rather than a reflection of a true increase in incidents.

Findings: Three (3) hospitals were cited for deficiencies in this area including the failure of two (2) hospitals to report an incident. Six (6) hospitals received cautionary feedback regarding the timeliness of the required follow-up reports. Five (5) hospitals were found to be compliant with the requirements in this area. The Department has identified the need to clarify the regulatory requirements regarding the definitions of reportable incidents.

## PSYCHIATRIC SERVICES

Psychiatric hospitals and hospitals with psychiatric units were reviewed by survey staff for assessment, treatment planning, social services, progress notes and discharge planning. Nine (9) of the fourteen (14) licensed hospitals operate psychiatric units The surveyors noted concerns with the psychiatric services at many of the hospitals. Hospitals' treatment plans did not consistently establish treatment goals that are measurable, and often failed to identify specific treatment modalities to be used. Surveyors also noted concerns with occasional failure to complete a social history in the record. These are all CMS, as well as state, requirements. While the concerns noted by the survey staff were generally noted at most hospitals surveyed, only one (1) hospital received a formal deficiency in this area. Nonetheless, this appears to be an area where hospital practices need general attention and improvement.

The surveyors noted that there was a broad consensus among hospital officials that the mental health service system in Rhode Island is nearing a crisis, particularly for children and adolescents. This input is included under "CEO CONCERNS/COMMENTS" elsewhere in this report.

Findings: Of the nine (9) hospitals with psychiatric units, one (1) received a deficiency, four (4) received cautionary feedback, and five (5) were determined to be in general compliance with the regulations regarding psychiatric services. Cautionary guidance was provided to the four hospitals noted above regarding needed improvements in the

specificity in treatment planning, measurability of goals and documentation of treatment provided.

## RESTRAINT USAGE

Recently, the federal Center for Medicare and Medicaid Services (CMS) issued a new Condition of Participation on patient rights. CMS's new requirements detail the conditions and limitations regarding acceptable use of patient restraints. In addition, the Department has developed draft regulations addressing the use of restraints. Accordingly, the Department determined that it was an appropriate area for review.

The Department did not find that the use of restraints at most hospitals was at a level that raised concern. However, two hospitals were cited with deficiencies for restraining patients without physician orders. In another, the surveyors provided cautionary feedback regarding failure to demonstrate good assessment of the need for restraint and that the restraint applied was the least restrictive option available. Several of the hospitals are in the process of developing new policies and procedures to comply with the CMS regulation. The survey staff reviewed the new policies at these facilities and found them inadequate in several respects. These hospitals were provided with informal feedback and some assistance in understanding and complying with the CMS requirements This review has allowed us to provide guidance to the hospitals and assist them in the development of their policies before it becomes a federal enforcement issue.

Findings: Two (2) hospitals received deficiencies for the use of restraints without a physician's order. Six (6) hospitals received cautionary feedback regarding the assessment process and the use of the least restrictive approach to restraint usage. Six (6) hospitals were determined be in compliance with these requirements.

## PHARMACY SERVICES

A full inspection was performed by the Department's registered pharmacist in all pharmacies as well as the satellite or night pharmacy and the parenteral area if one existed.

Hospitals that operate parenteral pharmacies (i.e., those engaged in the practice of admixtures and dispensing of sterile parenteral solutions intended for administration to patients) were also inspected for the preparation of sterile solutions. Adverse Drug Reports (ADRs) were reviewed for the years 1999 and 2000. Clarification of ADR'S was very explicit as to the types of classes as well as to the results of ADR occurrences (i.e., those resulting in allergic and toxic reactions, untoward side effects, idiosyncratic and drug interactions.) All ADR"S are reported to the hospitals' pharmacy and therapeutics committee every two months. Of the more than 1370 validated adverse drug reactions, there were 14 severe (life threatening, contributing to death or permanent injury) adverse reactions reported to the Department.

A medication error is a preventable event that may cause or lead to inappropriate medication use or patient harm, while the medication is in the control of the health care professional, patient or consumer. A review of medication errors was done for the year 2000. There were 886 incidences reported. The pharmacies were responsible for 55 of the reported incidences of medication errors. The vast majority of noted medication errors never affected patient care as the inappropriate medications were identified via intervention prior to administration to patients. The pharmacy errors involved mislabeled drugs, medication being placed in the wrong section of the Pyxis machine (automated dispensing machine located on patient units) and medication being labeled incorrectly with wrong strengths. Incident reports were reviewed for errors in narcotic count, order entry or procedural mistakes, such as in the loading of the Pyxis machine.

Findings: No deficiencies were cited with respect to hospital pharmacies.

MANAGEMENT OF CRITICAL CARE UNITS

Hospitals were surveyed for compliance with the requirement that special care units be under the direction of a physician qualified by training and experience in the specialty care. Twelve (12) hospitals operate "critical care units" subject to the regulations. We have focused on Critical Care Units (CCU). There are 2 components to this part of the review: the qualifications of the medical director, and the written position description delineating the authority and responsibility of the director.

On first survey, eleven (11) of the twelve (12) hospitals with critical care units were found to have well-qualified medical directors for their CCUs. Seven (7) have developed appropriate position descriptions that outline sufficient authority and responsibilities to allow the physician to direct and manage the unit as required. Five (5)) of the hospitals did not have appropriate written position descriptions, but through interviews, it was determined that the directors of these units exercise appropriate authority.

One (1) hospital did not have a position description authorizing the director to exercise appropriate control over the functioning of the unit. The surveyors determined this to be an oversight and the hospital corrected this matter by revising the job description.

Findings: The Department found most hospitals visited were in compliance with the regulatory requirements in this area. Several hospitals did received informal cautionary advisories; however, no deficiencies were cited.

DISCHARGE PLANNING

This area was included in the review because patients are facing earlier discharge and increasingly require continuing care. Recognizing this, several years ago the Center for Medicare and Medicaid Services made discharge planning a condition of participation in the Medicare program. In spite of the importance placed on this area, in the recent past, hospitals have been found out of compliance with at least some, if not all, federal

discharge planning requirements. Current state regulations are not nearly as comprehensive, but remedies have been proposed in a current draft.

Typically, a good discharge planning process includes:

- screening mechanisms designed to identify all patients at risk for having care needs following hospital discharge,
- timely evaluations of high risk patients (i.e., that commences upon or shortly after admission), that assesses actual needs, and gathers information for discharge plan development,
- discharge plans that include input from patient and/or family and/or significant others.

The process should also include a quality improvement component and formal policies and procedures that describe the above process.

The team identified random failures in discharge planning related to identification of patient needs, timeliness of evaluation, and failure to include patient/family/significant other participation in the plan. In these cases, medical records include plans that are developed and implemented with no evidence that the patients' actual needs were identified, and/or that alternatives to the chosen discharge plan were discussed with patient/family/significant others. In some cases, medical records reflect that discharge plans were developed on the day preceding or day of discharge. These cases demonstrate hospitals' failure to evaluate patients' discharge needs "early on" and to plan for meeting those needs in an appropriate fashion. Some records reflected the initiation of discharge planning late in the hospital stay, and some records reflect a failure to identify post-discharge needs. Several hospitals received cautionary feedback regarding these findings. One hospital received discharge planning related deficiencies and this hospital will remain under review until full compliance is achieved.

Findings: One hospital was cited with a deficiency related to discharge planning and remains under ongoing review. In addition, several hospitals received cautionary feedback regarding random findings.

EMERGENCY SERVICES

All hospitals were reviewed for compliance with Section 22.0 Emergency Service of the hospital licensing regulations. Surveyors found the following evidence of non-compliance at several hospitals:

1) Failure to post signage related to emergency room (ER) charges (e.g., failure to notify patients that additional "professional service" charges may apply);
2) Failure to post poison antidotes;
3) Failure to conduct annual in-service education regarding pre-hospital care protocols; and,
4) Failure to check "crash carts" in accordance with regulation.

Findings: Although the above findings would ordinarily be cited, these areas of non-compliance were not cited since these deficiencies were either corrected immediately or the surveyors were assured they would be. These deficiencies are easily correctable and they do not reflect system failures.

In addition to conducting compliance reviews, the Department staff conducted interviews with the chiefs of emergency medicine and ER nurse managers. They were asked to identify areas of concern that should be brought to the attention of the Department. Their concerns include the following:

1) Personnel at several facilities noted considerable difficulty in finding appropriate follow-up care for people who present to ER's with substance abuse and who also have mental health components (depression, suicidal ideation). Finding in-patient treatment for such patients reportedly centers on the availability of insurance coverage. According to several individuals interviewed, the type of insurance coverage frequently can determine the nature and setting of care. Further complicating matters is that many of these patients have chronic conditions. Also, depending on geographic location and population, problems finding appropriate and timely inpatient placement for adolescents and children were expressed.

2) Dealing with companies that manage mental health benefits is also reportedly an increasingly frustrating matter for ER attending physicians. These companies cause major delays by not calling back promptly, by having additional managed care personnel call back (slowly) to ask additional (and, not infrequently, inappropriate) questions and generally forcing the ER physicians to "jump through hoops". When the patient's admission is approved, very limited time is granted (1 day) and hospital staff has to spend hours back on the phone the next day justifying their pleas for additional inpatient days for the patient.

3) Another factor impacting resource availability is "holding" admitted patients in the ER due to bed shortages on hospital's inpatient units. While holding patients can and does occur all year long, the frequency and volume increases during certain months. How the patient is cared for, who maintains responsibility for the patient under different circumstances was discussed during each survey. All of these factors place increased competing demands on the ER staff whose primary responsibility is to triage, treat/stabilize, and transfer/discharge individuals brought to the facility in need of emergency care.

4) The closing of hospital ER services due to overcrowding and the "diversion" of EMS vehicles to alternative hospitals can often quickly overburden those ERs that remain open. Survey staff noted that the ER staff interviewed at six hospitals raised concerns about the impact of diversions on their operations. While hospitals claim to use reasonable criteria for diversion, the interviews revealed a potential need for improved coordination and cooperation among hospitals and

EMS services. The Department is presently reviewing this matter with the assistance of the Hospital Association of Rhode Island.

5) Several acute hospitals expressed frustration with the shortage of available adolescent and pediatric psychiatric beds. As described to the Department's survey staff, the problem begins in the community where there is an acute shortage of pediatric psychiatrists, and a shortage of residential care/ follow-up. The Department's survey of the two psychiatric inpatient hospitals substantiated the acute care bed shortage. Both were essentially fully occupied and reported their high occupancy levels as normal.

6) Hospital ER staff report that patients and families are regularly becoming impatient waiting for service/care. In their frustration, a growing number of these individuals become rude to staff and others. Hospitals report that substantial limited staff is required to attempt to calm the increasingly anxious visitors to the ER causing tension in an already chaotic environment. One hospital suggested the need for a statewide public education initiative regarding appropriate use of ER services and informing the using public of reasonable service expectations for this stressed setting.

7) The state's trauma center reported continued inappropriate use of their facilities for the holding of inebriates. It was stated that this is a poor use of costly resources and is unnecessarily disruptive to the primary mission of the facility. It was suggested that the State needs to provide for an appropriate site for the care of inebriates.

LABELING OF IV SOLUTION BAGS

Recently, the Department had issued a deficiency to a hospital for its failure to label intravenous (IV) solution bags. None of the surveyed hospitals were non-compliant with respect to the labeling of IV bags. It appears that the previously noted problem at the cited hospital was an isolated practice.

Findings: All facilities surveyed were in compliance with respect to appropriate labeling of IV solution bags.

COUNTERSIGNING OF TELEPHONE ORDERS

Recently, during the process of revising the regulations for hospitals, the Department had been advised that the requirement for prompt signing of physicians' telephone orders was unreasonable. This was a concern because, not only is this a state requirement, but a federal Medicare requirement also mandates the prompt signing of such orders. Following discussions of hospitals' concerns regarding this requirement, the Department is proposing regulatory amendments that will require the ordering practitioner to sign the telephone order by the "end of the next working day."

Findings: The Department cited deficiencies at two (2) hospitals for failure to have physicians countersign telephone orders within twenty-four (24) hours. All other hospitals (12) were in compliance with telephone orders being signed within 24 hours as currently required by regulation.

## MEDICAL STAFF REAPPOINTMENTS AND HEALTH SCREENING

Physicians' credentialing files are reviewed to determine if the requisite hospital established processes are followed in making appointments and re-appointments. Surveyors reviewed several randomly selected files at each hospital. Two (2) hospitals were cited for demonstrated patterns of failure to conduct staff re-appointing and recredentialing on a timely basis. These non-compliant facilities are affiliated with each other and had centralized the credentialing and reappointment process – the survey indicated that the centralized process is not functioning appropriately. At the remaining twelve (12) hospitals, lapses were determined to be minimal and no deficiencies were cited regarding medical staff reappointments at those hospitals.

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Ten (10) of fourteen (14) hospitals were determined to be deficient with regard to health screening requirements for physicians and other staff. Appropriate health screening for staff that has patient contact is an important element of infection control – the requirements seek to protect patients, who often have increased susceptibility to disease, from acquiring infections from hospital staff. At one hospital visited, the survey staff noted that evidence of vaccinations was kept in the credentialing files (at other facilities this information is kept in a separate health file). At this hospital, many physicians had failed to provide evidence of immunity to communicable diseases or TB testing, as required by regulation. A deficiency was cited and this element was added to our survey process. Ten (10) hospitals were cited with deficiencies relative to the health screening requirements for the medical staff. One hospital received cautionary feedback, as two of twelve files reviewed did not include documentation of immunity as required. One hospital had erroneously excluded consulting staff from the screening requirements. The clear intent and wording of the regulation is that the requirements apply to all individuals who have direct contact with patients.

Findings: Ten (10) hospitals received deficiency citations regarding the health screening of their medical staff. Four (4) facilities were found to be compliant with the requirements for health screening.

## CEO CONCERNS/COMMENTS

During the course of site visits, the surveyors met with chief executive officers and vice presidents to elicit their feedback on issues of concern to the Department, and to allow them to share concerns with the survey staff. Hospitals were encouraged to share issues for which a Department of Health initiative or General Assembly action might prove

helpful. The following are the more significant topics that have been identified by the hospitals in these dialogues.

Staffing

The extent of staffing concerns varies greatly among hospitals, with some facilities feeling shortages more acutely. Hospital executives generally noted that the market for nurses (especially in specialties such as Emergency Room -ER, Operating Room-OR and Critical Care) and technicians (laboratory, OR, radiology, etc) is tight, but that the impact across hospitals varies. Problems with hospital recruitment and retention of nurses vary somewhat by geographic location, but more importantly, success at attracting and retaining staff appears to be more related to staff morale and nurses' perceptions about the working conditions at particular facilities. Hospitals reported that pharmacists are in extremely short supply; pharmacists are attracted to the significantly higher salaries offered by the retail pharmacies. One hospital executive expressed concerns that the move to establish the Pharm. D. degree as the base level education for pharmacists will further exacerbate supply problems, at least in the near term Hospitals also reported significant levels of turnover in the non-professional areas (housekeeping, mental health workers, food service, etc.)

Some hospitals stated that they are using "traveling" (i.e., licensed staff drawn from other states provided from national agencies) nurses, laboratory technicians and surgical technicians. Some hospitals are also using local agency or "pool" nurses and others are relying on overtime to cover specialty areas such as Emergency Departments.

One hospital stated that staffing has improved and they credited several initiatives, including an expanded program for novice nurses (6 weeks), and a "feeder" program to encourage medical/surgical nurses to move into specialty areas through training and preceptor programs in the hospital (e.g., med/surg-to-MAXIcare-to-CCU). This hospital also credits an initiative to improve "quality of life" of staff as having an impact upon staff attitudes – where no one previously recommended employment at their hospital, staff are now encouraging friends and colleagues to join the staff.

One CEO stated that his facility was staffed as well as, if not better than, other area hospitals. He stated the hospital had always been able to meet their planned nurse/patient ratios. This facility reported that it had recently increased the numbers of nurses relative to patients in response to patient needs and were successful in maintaining full staff levels. The hospital noted, however, that recruiting pharmacy, radiology and surgical technicians was difficult.

Another hospital felt that recent initiatives to increase hospital services and recent affiliation with another hospital enhanced their recruiting ability – the facility reported it has received inquiries from specialty-trained nurses who would like to join the staff at the earliest opportunity.

A psychiatric hospital stated that third party reimbursement is lower for psychiatric services than it is for general hospitals, making it hard for the psychiatric hospitals to compete with salaries offered to nurses in general hospitals.

The state hospital identified particular staffing issues that no other hospitals reported – these were related to state hiring practices, not availability of applicants to fill jobs. When a person leaves a position at the State hospital, the position cannot simply be filled; when more staff is needed, positions cannot be created. With the FTE cap and the Emergency Hiring Council being required to review every vacancy to be filled, the hospital is chronically short-staffed. At times, the hospital indicated that it has had to slow admissions in order to be able to meet the care needs of patients.

Physician Recruitment

Physician recruitment issues vary by locale in Rhode Island. Hospitals located in the greater Providence area reported having no recruitment problems. Growing communities need more primary care physicians, some suburban community hospitals have difficulty providing all the specialists they need for ER on-call coverage, and hospitals located in southern Rhode Island report psychiatrists and obstetricians are in short supply. Hospitals in the northern portion of the state are finding that primary care physicians establishing new practices in that area are demanding more clinical services and higher quality services from the local hospital.

Some hospitals are aggressively recruiting physicians to their communities, and may offer financial assistance. Through affiliation with another hospital and improving services, one hospital finds it is attracting Providence-based physicians along with many of their patients who used to travel to Providence to receive care from these physicians.

Hospitals reported that the extremely limited number of child psychiatrists available to provide outpatient services is an acute problem, and, in fact, may be approaching crisis level. Even though many physicians are trained in child psychiatry here in Rhode Island, they often leave the state, particularly if they intend to practice in an outpatient setting. The reimbursement for outpatient services in Rhode Island was characterized as "pitiful." Hospitals noted that the provision of psychiatric services for children requires many "unpaid" hours (e.g., necessary contacts with family, schools, etc.) that are not required for adult services. Exacerbating the situation, hospitals reported that many community psychiatrists are dropping the child component of their practices or are limiting their practice to "fee for service" patients. As a consequence, children often receive outpatient care provided by non-physician counselors and clinicians or by general (adult) psychiatrists. These children may not be well managed and may decompensate to a point at which hospitalization is necessary. Post hospitalization outpatient care for children is extremely difficult to arrange. Appointments for outpatient follow-up care often cannot be scheduled at discharge and, when available, waits of a month or more are common.

The hospital that specializes in providing children's psychiatric care reported that when outpatient services were reduced over the last eighteen months, more children had to be denied care. This facility reported that there were 388 admissions in 1988 and 1000 in

2000. While they admitted 1000 children in 2000, they had to turn away 850 children seeking inpatient care. The facility stated that some re-admissions could have been prevented with better outpatient management. The facility is concerned that this year there may be serious problems due to lack of available services.

Inpatient psychiatric care has changed for both children and adults. Hospitalization is no longer the definitive treatment. The role of the hospital now is to keep the patient safe, do good assessment, get the patient on the right medications, and discharge to an appropriate setting for care. With the recent reduction in available outpatient treatment, demand for inpatient treatment is likely to increase.

## Interpreters

Most hospitals report little problem with foreign language interpreters. Several hospitals reported that they have actively recruited bilingual personnel, especially registration clerks and clinic nurses. Some deliberately try to avoid the use of non-professional staff or family members as interpreters. Foreign language interpretation is provided by staff, patient families, community-based interpreters or through the AT&T Language Line. One hospital reported it had installed speaker phones on every nursing unit to accommodate this service.

Some hospitals reported difficulty in finding persons who can sign for the deaf and hearing impaired. A "licensed" person who can sign is hard to come by and one can wait a very long (and unacceptable in a health care setting) time to get someone. It has been reported that 1996 enactment of licensure requirements for Interpreters for the Deaf (Chapter 5-71) has reduced the number of previously available interpreters.

During 2001 the General Assembly passed legislation setting specific requirements for the provision of interpretive services. The Department, in collaboration with interested parties, is presently developing regulations to implement these new requirements. The new requirements take effect 1 January 2002.

## Financial – Reimbursement Issues

All hospitals noted strong concerns regarding the inadequacy of third party reimbursements for inpatient and outpatient services. This concern also included payments provided for preventive health care including primary care, obstetrical services and psychiatric services. Hospitals were concerned with the lack of coordination and management of patients across outpatient settings. Activities related to coordination, referrals and sharing of information are not reimbursed, thus there is a lack of incentive to share information. This can result in tests unnecessarily being repeated and patients coming to the hospital that didn't necessarily have to be hospitalized (e.g., asthmatic children who could have been managed as outpatients if better coordination, management and reimbursement systems were in place.)

Hospitals noted that they attempt to provide the care required by each patient regardless of third party controls and directives. Unfortunately, they noted that the insurers can control the financing of service delivery and too frequently deny reimbursement after the fact. In some instances, hospitals claim that the third parties do not provide coverage for new and clinically superior therapies that the hospitals believe are necessary for patient care. As a consequence, hospitals do not receive reimbursements for these services. This occurs most frequently in the provision of oncology services where there is relatively rapid development of treatment modalities.

Hospitals are very frustrated over retroactive decisions by insurers to downgrade or deny payment. In some cases, patients are downgraded, then upgraded only to be downgraded again – these changes occur day to day. Hospitals noted that it is impossible for the hospital to discharge to skilled care and readmit on a day-by-day basis. Unilateral decisions by insurers with significant market power are causing problems for the hospitals. The hospitals report that insurers skirt the required process of discussion with the attending physician and that appeals are not useful. When denials for payment are made retroactively, the patient has already received the care that was deemed by the physician to be warranted, then the insurer denies payment – sometimes long after the fact. As a result, the patient gets the services that both the patient and physician desired, the insurer pays a lesser amount, and the hospital suffers.

Hospitals also noted problems with billing issues. They are required to submit the so-called "clean claim" within a prescribed amount of time. Insurers impose delays on the hospital's ability to meet the insurers' time lines. For example, an insurer will give authorization verbally, but give no authorization number and then take up to two weeks or more to provide the number, which the hospital needs to submit the claim

Another reimbursement issue that hospitals noted is refusal of insurers to pay for hospital-based outpatient services, such as laboratory testing or magnetic resonance imaging. Hospitals have to inform patients, who may be having other procedures done at the hospital, that they can not have their testing done at the hospital, but that they must go to an off campus provider within the insurers limited network for such services. Hospitals note that this is often inconvenient for patients.

Hospitals stated that some insurers are not approving admissions to specialized rehabilitation centers. Some will approve only acute hospital care or skilled nursing care, regardless of physician opinion. Hospitals noted that some patients may do better with a short intensive stay in a rehabilitation center rather a longer, less intensive stay in a skilled nursing facility. Typically, the only patients approved for care provided in a rehabilitation center are those severely debilitated with multiple medical problems. This changes the complexion of rehabilitation centers as well as the job and satisfaction of the rehabilitation centers' staff.

Likewise, hospitals stated that insurers are refusing to allow day or partial hospital care for psychiatric patients. Again, even in instances where physicians feel that this level is

most appropriate (e.g., to treat substance abuse), insurers often will reimburse acute or outpatient care only.

Hospitals also reported that they must be extremely aggressive in obtaining and keeping third party approvals, and that the administrative costs to just get reimbursed are becoming quite significant for the hospitals.

The lack of competition among private/commercial insurers (and resultant dominant market power) was noted by several hospital executives to be a fundamental, underlying cause of many of the third party reimbursement issues experienced by hospitals.

Miscellaneous

Additional hospital comments are presented below:

*Concern was expressed about the power outages that have occurred at hospitals this year. It was felt that significant problems are lurking in the future. Hospitals need an infrastructure that is safe and reliable – several CEOs expressed concern that the current provision of utilities is not as reliable as necessary.

*Hospital administrators voiced considerable concern with the number of Home Health agencies that have or that are closing. Rhode Island is, in their view, approaching a crisis in access to home care services. HEALTH should look at the implications of the growing shortage of available home health services.

* Rhode Island needs more community programs for psychiatric services (especially programs for children) and obstetrical services,.

* Schools do not do health and wellness teaching.

* Several hospitals suggested that it would be useful for the Department to have a greater role in providing education to hospitals, being an educator/facilitator for best practices, bringing about better coordination among providers, and bringing hospitals together to improve services. Some hospitals noted a variation in the manner in which the Department of Health relates to nursing facilities and hospitals. Hospitals would welcome a relationship similar to the one the Department enjoys with nursing facilities.

* There are not enough outpatient psychiatric services for children, which is increasing the need for inpatient care. Mental health services are fragmented. The state needs to build a better continuum.

* There are not enough child psychiatric inpatient beds available. In the absence of adequate bed availability, children either have to treated on a general pediatric unit or on an adult psychiatric unit. Neither option is appropriate.

* There are not enough residential beds available for substance abusers, especially

for women. Patients are requesting residential treatment and can not be accommodated due to inadequate capacity.

* The Medical Examiner will not release findings of autopsy to the hospital. Hospitals often must ask families or estates to obtain autopsy results and to release a copy to the hospital. This, of course, is not something the hospital would wish to do. It is unclear to the hospitals why the Medical Examiner cannot make autopsy reports available to hospitals. Hospitals also noted the frustration of all parties with respect to the timeliness of the conduct of autopsies and the availability of autopsy reports. Hospitals encouraged the Department to address this matter.

* Some hospitals are seeing increased, inappropriate demand for hospital inpatient placement of patients with dementia. This demand appears to emanate principally from skilled nursing facilities and mental health centers. Hospitals report that these patients do not require acute psychiatric care and that the demand may be indicative of supply and access problems in the state's system for providing community-based psychiatric services.

* Psychiatric practitioners want the state and federal government to embrace true parity for coverage of services for physical and mental illness.

* This past summer, several hospitals noted that they were experiencing new problems with the availability of drugs. Hospitals reported that it was difficult to obtain commonly used items such as succinylcholine, tetanus toxoid and epherine. Hospital executives speculated that the manufacturers were abandoning these products in order to produce drugs that provide a higher profit margin.

## V. OTHER INITIATIVES

The provision of additional personnel to focus on hospital issues would provide for additional opportunities to partner with the hospitals for quality improvement activities other than surveys. Several opportunities presented themselves during survey period and the Department of Health made its best efforts to use them to good advantage. This section of the Report presents a synopsis of those efforts.

### MRSA/VRE

Administrative staff at several facilities shared their concerns with dealing with the increase in infections caused by Methacillin Resistant Staphylococcus Aureus ("MRSA") and Vancomycin Resistant Enterococci ("VRE"). Both MRSA and VRE are particular strains or forms of these common bacteria that have developed "resistance" to the most effective antibiotics available to treat infections caused by these strains of bacteria. MRSA and VRE present significant infection control problems for hospitals and other health care facilities in Rhode Island and elsewhere.

Several hospitals have noticed an increase in MRSA and/or VRE cases. Hospitals noted that the rise in MRSA and VRE is affecting staffing needs (infected patients require more staffing time) and bed availability (isolation and cohorting of patients reduces a hospital's ability to make optimal use of its bed capacity.) The hospitals requested information regarding the extent of the problem in other hospitals and in nursing facilities, and appropriate strategies for controlling spread of these infections. Several hospitals requested assistance from the Department to initiate a multi-hospital effort to address this problem. As noted elsewhere, the Department has initiated actions in this area.

In late January, a hospital officer called the Division of Facilities Regulation to express a concern about the difficulty their (and presumably other) hospital had been having eradicating and controlling the spread of an infectious bacteria, Methacillin Resistant Staphylococcus Aurous (MRSA). One of the Department's hospital survey team members noted and confirmed that this had also been a concern of a hospital they had recently surveyed. A planning meeting was held that involved representatives from the hospital's administration and infection control staff and the Department's Division of Disease Control & Division of Facilities Regulation. The purpose of this meeting was to develop an organized and comprehensive response to this problem. On 7 March 2001 the newly formed MRSA Workgroup met. The Workgroup membership includes the Department's Division of Disease Prevention & Control and the Division of Facilities Regulation, the Medical Director of Rhode Island Quality Partners (The PRO), the Hospital Association of Rhode Island (HARI), and Rhode Island Hospital staff, which includes Dr. Len Mermel, a nationally recognized expert on MRSA. The goals of the workgroup are to: 1) determine the level of MRSA colonization/infection in Rhode Island's acute care, extended care, and community care settings, 2) understand MRSA transmission between these patient populations, 3) to review existing MRSA control guidelines and revise standards of practice where necessary, 4) establish a monitoring system for compliance with standards of practice, 5) reduce the incidence of MRSA colonization/infection.

Once the hospital guidelines are prepared, the Workgroup will meet again with representatives from the extended care and community care agencies to develop integrated MRSA guidelines for all three health care provider groups. This serves as one example of what can be done if there were a continuation of the hospital survey and support effort.

The analysis of hospital emergency room's (ER) policies and practices has become a second opportunity for development of a closer partnership between the hospitals and the Department of Health. The summer of 2000's hospital labor action planning, recent articles in national newspapers, bio-terrorism planning, allegations of ambulance services' casual attitude toward compliance with diversion declarations (supposedly because they are implemented so often) and the normally expected heavy load on ER's during the flu season focused the Department's attention on these issues. The recent terrorist attack on the country further emphasizes the need for cooperation and coordination between the public health authority and the hospital community,

It is the Department's intention to work with HARI to gather information to understand these issues. There is little information about the scope of the problems and what can be done to reduce diversion or coordinate diversions on a statewide basis. The Department will staff this project with survey team and staff from the Office of Emergency Medical Services at the Department of Health. Currently, the Department and HARI are working to define an appropriate approach for the proper analysis of this problem.

The Department believes that the establishment of an ongoing and regular presence of survey staff in hospitals is an appropriate and a high priority use of state resources that will be of significant value to all individuals and organizations that use, provide, or pay for hospital services in Rhode Island. The Department of Health, as the state health facility licensing agency, has a role and perspective in assuring the quality of hospital services that is vital. However, the Department cannot fulfil this statutorily defined role without a regular and ongoing presence in those facilities that is appropriately supported with state funds.

# Table I

## Hospital Incident Summaries
## Statewide 1994 - 2000

| Incident: | 1994 | 1995 | 1996 | 1997 | 1998 | 1999 | 2000 | Year Totals |
|---|---|---|---|---|---|---|---|---|
| Brain Injury | 0 | 0 | 0 | 2 | 1 | 4 | 0 | 7 |
| Mental Impairment | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Paraplegia | 0 | 1 | 0 | 0 | 0 | 1 | 1 | 3 |
| Quadriplegia | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 1 |
| Any Paralysis | 0 | 2 | 0 | 0 | 1 | 0 | 1 | 4 |
| Loss of use of | | | | | | | | |
| limb or organ | 0 | 0 | 1 | 2 | 0 | 4 | 2 | 9 |
| Complication | | | | | | | | |
| resulting in | | | | | | | | |
| extended stay: | | | | | | | | |
| Falls: | 3 | 9 | 9 | 19 | 19 | 11 | 29 | 99 |
| Other: | 3 | 7 | 3 | 3 | 2 | 10 | 33 | 61 |
| Birth Injury | 0 | 5 | 5 | 7 | 3 | 3 | 2 | 25 |
| Impairment of | | | | | | | | |
| sight/hearing | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Surgery on the | | | | | | | | |
| wrong patient | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 |
| Procedure not | | | | | | | | |
| ordered/intended | 1 | 5 | 5 | 0 | 0 | 7 | 1 | 19 |
| Elopement/kidnapping | | | | | | | | |
| Psychiatric | 13 | 12 | 12 | 7 | 3 | 3 | 5 | 55 |
| Minors | 0 | 3 | 2 | 2 | 2 | 5 | 1 | 15 |
| | | | | | | | | |
| Sub-total | 20 | 44 | 37 | 42 | 32 | 48 | 76 | 223 |

# Table I
# (Continued)
## Hospital Incident Summaries
## Statewide 1994 - 2000

| Incident: | 1994 | 1995 | 1996 | 1997 | 1998 | 1999 | 2000 | Year Totals |
|---|---|---|---|---|---|---|---|---|
| Reported to malpractice carrier Missed/delayed dx in Emer. Room | 0 | 4 | 6 | 11 | 6 | 4 | 4 | 35 |
| Missed/delayed dx elsewhere | 1 | 6 | 3 | 4 | 8 | 10 | 10 | 42 |
| Misread X-ray | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 2 |
| Misread lab/other | 0 | 1 | 0 | 1 | 4 | 6 | 2 | 14 |
| Delay in Rx | 0 | 0 | 0 | 2 | 2 | 2 | 2 | 8 |
| Falls | 3 | 6 | 11 | 12 | 7 | 6 | 1 | 46 |
| Adverse drug reaction | 0 | 3 | 2 | 3 | 2 | 1 | 3 | 14 |
| Nerve injury | 0 | 3 | 2 | 2 | 1 | 1 | 3 | 12 |
| Foreign bodies from procedure | 0 | 1 | 2 | 1 | 4 | 2 | 2 | 12 |
| Death | 1 | 20 | 17 | 16 | 20 | 27 | 20 | 121 |
| Other surgical complication | 2 | 7 | 10 | 13 | 9 | 15 | 7 | 63 |
| Perf./lac.during procedure | 3 | 5 | 6 | 6 | 7 | 6 | 3 | 36 |
| Other | 4 | 26 | 24 | 39 | 33 | 22 | 25 | 173 |
| Sub-total | 14 | 82 | 83 | 110 | 104 | 103 | 82 | 578 |
| Total (pages 1&2) | 34 | 126 | 120 | 152 | 136 | 151 | 158 | 801 |

# Table 2
## Statewide Reported Events

| Events | 1994 | 1995 | 1996 | 1997 | 1998 | 1999 | 2000 |
|---|---|---|---|---|---|---|---|
| Fire/Internal Disaster-Disrupt Pt. Care or harm to patients or personnel | 1 | 2 | 0 | 0 | 1 | 3 | 1 |
| Poisoning Patient(s) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Infection Outbreak | 0 | 0 | 2 | 1 | 1 | 0 | 0 |
| Strikes or other personnel disruption of services | 0 | 0 | 0 | 0 | 1 | 0 | 2 |
| External Disaster(s) or emergency situation effecting Pt. Care | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Termination of Services/ Utilities Vital to Safe Hospital Operations | 0 | 0 | 2 | 0 | 0 | 1 | 2 |
| Total | 1 | 2 | 4 | 1 | 3 | 4 | 5 |

# Table 3
# Safe Medical Devices

| | 1994 | 1995 | 1996 | 1997 | 1998 | 1999 | 2000 |
|---|---|---|---|---|---|---|---|
| Statewide Total | 4 | 11 | 7 | 3 | 11 | 15 | 8 |

CHART 1

# Total Incidents Reported Statewide

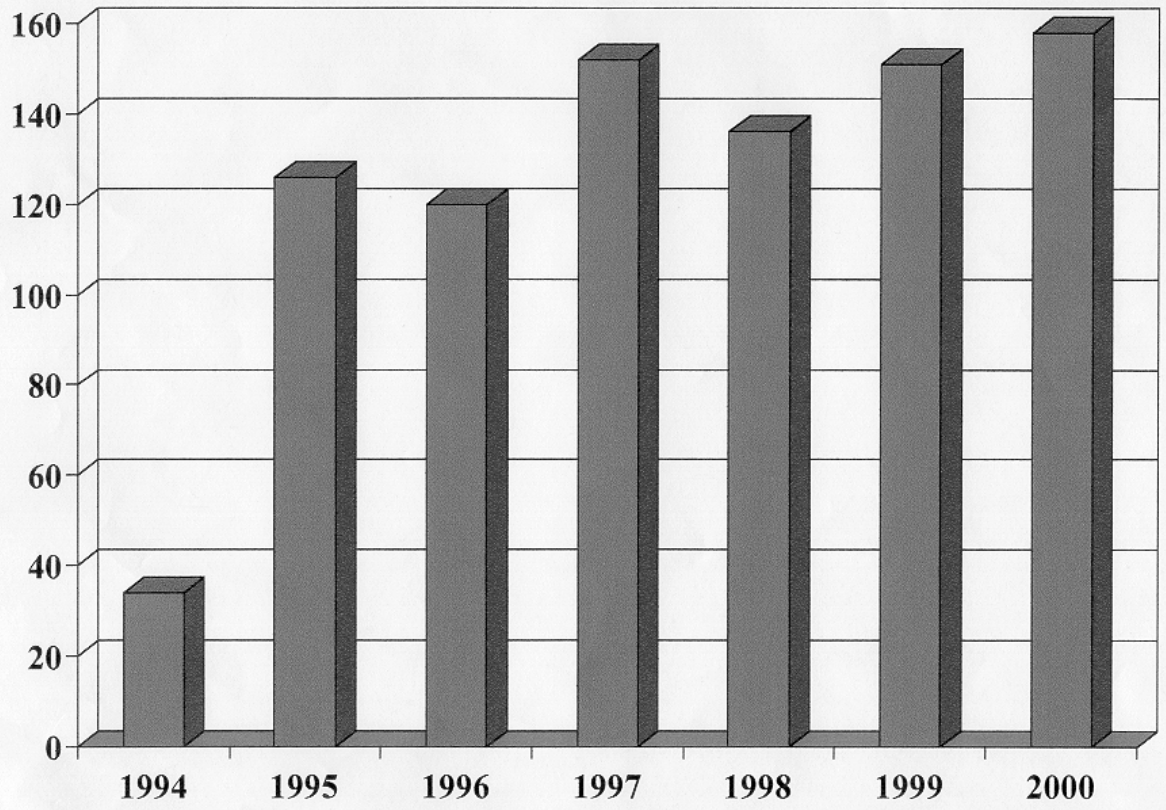


CHART 2

## Incidents Reported Statewide Other Than Reports to Malpractice Carrier

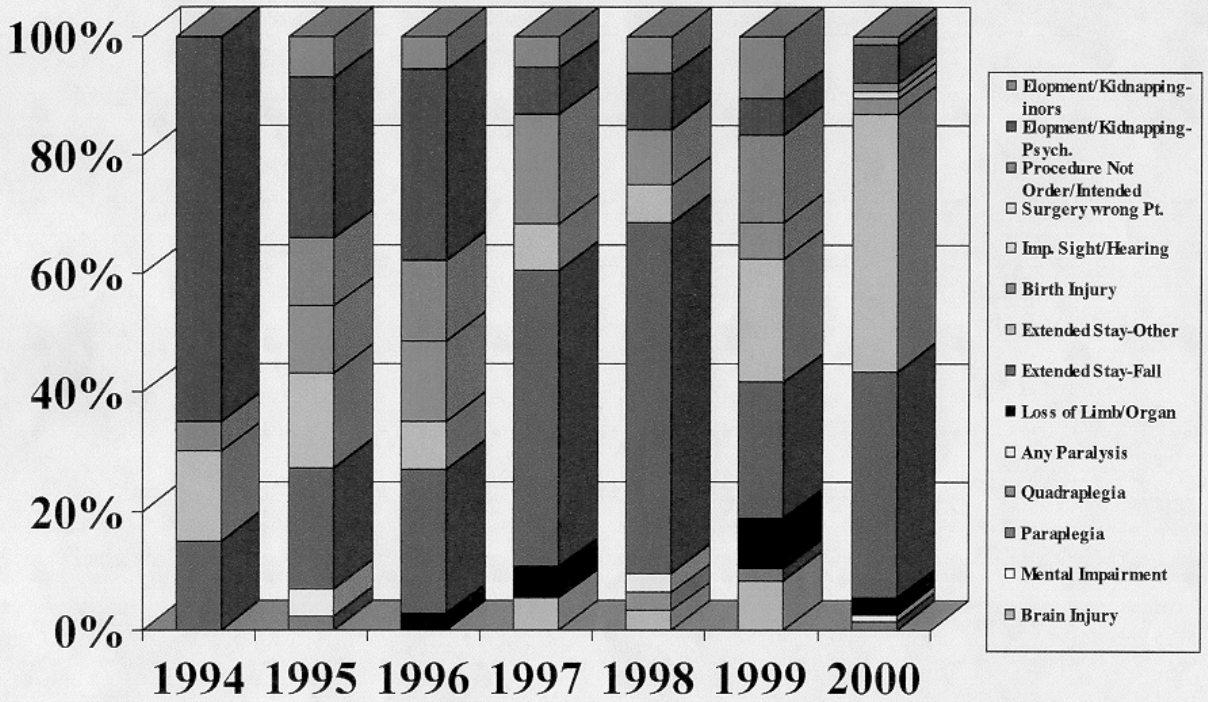
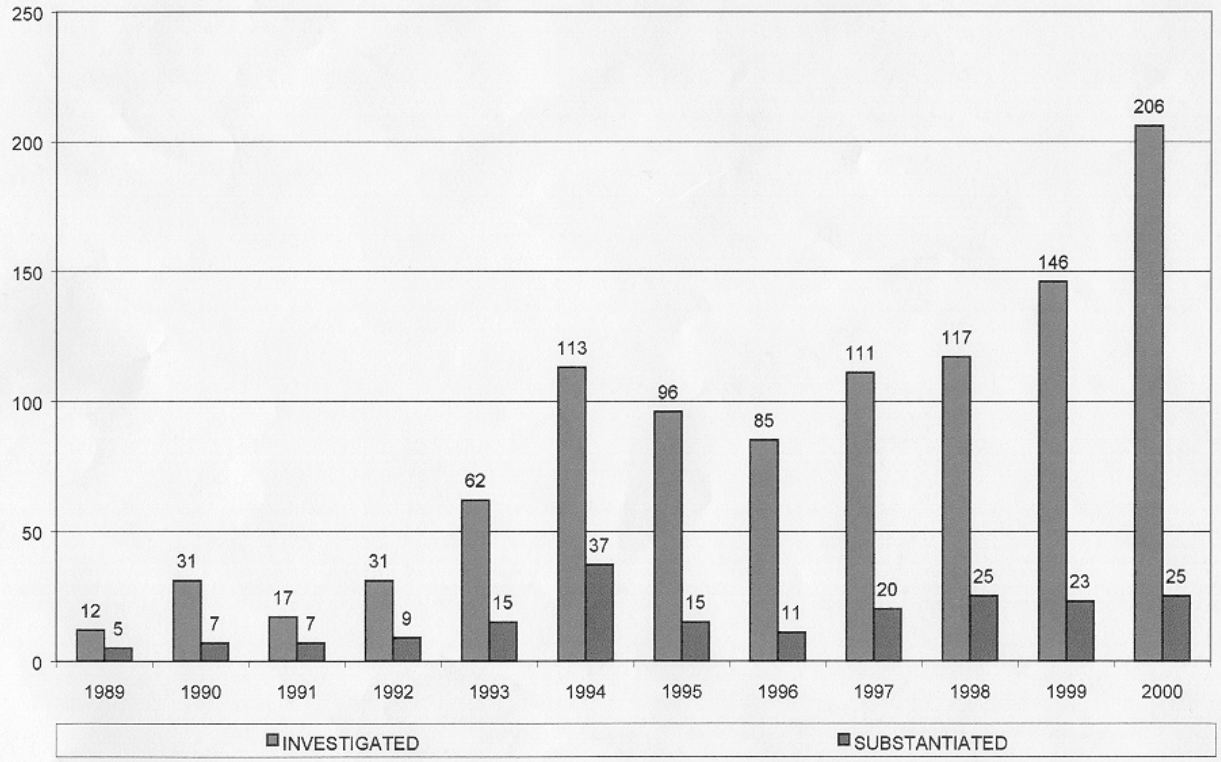


CHART 3


HOSPITAL COMPLAINTS IN FEDERAL FY
250
200
150
100
50
0
12
5
31
7
17
7
31
9
62
15
113
37
96
15
85
11
111
20
117
25
146
23
206
25
1989
1990
1991
1992
1993
1994
1995
1996
1997
1998
1999
2000
INVESTIGATED
SUBSTANTIATED

APPENDIX 1

State of Rhode Island and Providence Plantations

General Assembly
STATE HOUSE
PROVIDENCE, RHODE ISLAND 02903

June 16, 2000

Patricia A. Nolan, MD, MPH
Director of the Department of Health
3 Capitol Hill
Providence, RI 02903

Dear Director Nolan:

The Assembly has appropriated $300,000 in Article 1 of 2000-H 7862, Substitute A, as amended for a Hospital Care Consultant Report to provide a review of hospital errors and the reporting of same for Rhode Island's hospitals. The funding appears as a separate line item in the FY 2001 Appropriations Act within the Health Services Regulation program.

Rhode Island General Law 23-17-40 requires reporting to the Department of Health of any hospital incidents and errors that resulted in patient injury. While the statute is fairly thorough, only a few of the hospital errors that are causing injuries are being reported each year. In 1998 only six errors were reported, after deducting falls and kidnappings from report totals. Hospitals are not reporting errors, clearly ignoring the letter and spirit of the law. The Department of Health needs to provide additional oversight to this issue to enforce the intent of the statute. The Department of Health needs to prioritize oversight of hospitals and address medical errors causing injury in our state.

It is the intent of the Assembly that the Department of Health addresses the issue by requiring a consultant to:

- Conduct investigations, surveys and audits of hospital records and staff to determine and ensure compliance of RIGL 23-17-40,
- Study what changes are necessary to improve the current reporting statute, and report back to the Assembly any recommended changes,
- Review of reports from hospitals in Rhode Island, as well as studies from the National Academy of Science Institute of Medicine and elsewhere, for the purposes of providing analysis with the intent of improving overall patient care in Rhode Island hospitals,

- Conduct investigations, surveys and audits of Rhode Island hospitals for purposes of determining the unreported errors and mandating remedial action,

- Promulgate rules and regulations as a part of remedial action, when necessary, to fulfill the state's duty to provide safer systems of health care,

Once the review is completed, the consultant shall submit a formal report to the Assembly detailing all findings and recommendations.

Sincerely,

Representative Antonio J. Pires
Chairman
House Finance Committee

Senator J. Michael Lenihan
Chairman
Senate Finance Committee

APPENDIX 2

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

# D E P A R T M E N T O F H E A L T H

*Safe and Healthy Lives in Safe and Healthy Communities*

**Patricia A. Nolan, MD, MPH**
**Director of Health**

16 August 2000

The Honorable Antonio J. Pires
Chairman, House Finance Committee
The Honorable J. Michael Lenihan
Chairman, Senate Finance Committee
State House
Providence, RI 02903

Dear Representative Pires and Senator Lenihan:

Thank you for the explanatory letter concerning the line item on hospital care in the FY 2001 budget. I have carefully reviewed the issues with the staff of the department and had a preliminary conversation with Ed Quinlan of the Hospital Association. The advantage we have in Rhode Island lies in the Health Care Quality Program already established by the department pursuant to statute. We are acutely aware of the importance of linking the concerns about medical errors with the overall concerns for quality of care.

Our plan is to complete the necessary reviews of existing documents, survey reports, complaints, and medical error and incident reports as quickly as possible. With the limited funding available, we do not expect to have a single consultant organize and conduct all of the activities required to complete the tasks set forward and prepare a report. We will concentrate on gathering the information, including on-site surveys of selected hospital services in an expeditious manner, employing staff expertise and contracted medical record abstractors.

At the same time, we will seek a consultant to review the data and develop a report for the Department, the Governor and the Assembly. We have the following criteria for a consultant:

Knowledge of the hospital quality environment, including accreditation, clinical continuous quality improvement and clinical error reduction;

No direct connection to Rhode Island hospitals (conflict of interest);

Systems orientation, and

Availability for quick turnaround.

We are hoping to have a consultant selected shortly.

CANNON BUILDING, Three Capitol Hill, Providence, Rhode Island 02908-5097
Telephone 401-222-2231, FAX 222-6548 ~ Web Site: www.health.state.ri.us
Hearing/Speech Impaired, Call 1-800-745-5555 (TTY)

It is important to respond to the concern about hospital reporting raised in your letter. The Department of Health has had very limited capacity to respond to reports of incidents in hospitals. Our existing resources are deployed in a manner to maximize the use of federal monies.

As a consequence, most of our survey and inspection activities are focused on long term care. To make best use of extremely limited resources available for hospital oversight funded only with state monies, the department promulgated hospital regulations, consistent with section 23-17-40, that requires reporting of incidents with significant patient consequences.

We do not have direct evidence that the hospitals are ignoring the reporting requirements currently in place. With essentially similar statutory reporting requirements, the New York State Health Department receives an average of 7.6 incident reports per 1,000 discharges, while the Rhode Island rate is 1.8 per 1,000 discharges. This observed difference in reporting rates does raise some questions regarding the completeness of hospital incident and events reporting. We will be examining hospitals' internal incident reports and quality improvement activities to assess the completeness of reporting.

As we reported during the legislative session, we in the Department of Health believe that the hospital oversight process is under-resourced in comparison to its importance to health. Hospitals remain a critical component of our health care system, and they are financially stressed. Our goal is to provide the framework for oversight of clinical quality of care in hospitals without an excessive strain on the finances of either the state or the hospitals. Our consultant report will address that challenge.

Sincerely,

Patricia A. Nolan, MD, MPH

Patricia A. Nolan, MD, MPH
Director of Health

PAN:bjs

cc: Ed Quinlan
Peter Quattromani

## APPENDIX 3

Excerpted from: The New York Patient Occurence Reporting and Tracking System Annual Report, 1999

The New York Patient Occurrence Reporting and Tracking System (NYPORTS) is an adverse event reporting system implemented pursuant to New York State Public Health Law Section 2805-l, Incident Reporting. For the purpose of NYPORTS reporting, an occurrence is an unintended adverse and undesirable development in an individual patient's condition occurring in a hospital. Most occurrences reported are meant to be tracked and trended as groups and are reported on a short form. More serious occurrences defined as patient deaths or impairments of bodily functions in circumstances other than those related to the natural course of illness, disease or proper treatment in accordance with generally accepted medical standards are investigated individually and require the hospital to conduct a root cause analysis. All adverse events are not medical errors and should not be considered as such. NYPORTS does collect reports on medical errors, but the volume of medical errors in the system is a very small percentage compared to the overall volume of reporting. It should be noted that New York State Public Health Law Section 2805-m Confidentiality prevents disclosure of incident reports under the Freedom of Information Law.

New York State has had a long history of requiring hospitals to report and initiate actions based on adverse events occurring in their facilities. Since October 1, 1985, a mandatory incident reporting system has been in place in New York State. The incident reporting system was initially a paper reporting system; later, an email-based system was developed. Neither of these systems allowed feedback to the hospitals which limited the use of the data for quality improvement. At the direction of Governor Pataki, through a regulatory reform effort, NYPORTS was created to simplify reporting, streamline the coding, coordinate with other reporting systems to reduce duplication, and most importantly, allow hospitals to obtain feedback on their own reporting patterns and compare them with other facilities in the region and the State. Despite these significant improvements, not all hospitals are complying with statutory reporting requirements.

The development of the electronic internet-based system began in 1995, utilizing a statewide workgroup of industry experts and a consumer representative. It was extensively field tested and refined and was implemented on a statewide basis in April 1998. The new system made it easier for hospitals to report adverse incidents, as required by law, and to obtain comparative data. The under-reporting noted in this report appears to represent deliberate failure to report adverse incidents by certain facilities.

With the issuance of the Institute of Medicine's (IOM) Report, To Err is Human, in late 1999 national attention has been focused on the NYPORTS system. As an adverse event reporting system, NYPORTS collects data regarding a wide range of occurrences. Medical errors, which are the focus of the IOM report, represent a relatively small proportion of events reported into NYPORTS. Significantly though, NYPORTS therefore provides hospitals with a tool to reduce medical errors. Thus, through proper usage of the NYPORTS system and process hospitals are aided in improving the safety of patients.

This report is the first public report to be issued from the NYPORTS system. It gives an overview of the background for the system and includes some initial data analyses. It is imperative for all hospitals to report completely into NYPORTS. If data are not reported completely and accurately, it is difficult, if not impossible, to estimate the occurrence frequency or the occurrence rate (number of occurrences/ number of admissions or number of occurrences/number of procedures of a given type) for various kinds of patients. This impedes the determination of which occurrence codes should have the highest priority for quality improvement efforts and exacerbates efforts to measure improvement that has occurred as a result of information derived from NYPORTS. Unfortunately, an analysis of 1999 data includes significant underreporting, particularly by hospitals in the New York City Metropolitan area. There are large regional variations in reporting – three times greater in some parts of the State than others – that can only be explained by

# APPENDIX IV

# HOSPITAL ON-SITE SURVEY SCHEDULE

| | |
|---|---|
| Jan 2-4, 2001 | The Westerly Hospital |
| Jan 8-10, 2001 | South County Hospital |
| Jan 16-18, 2001 | Kent County Memorial Hospital |
| Jan 23-25, 2001 | Roger Williams Hospital |
| Jan 30 – Feb 1, 2001 | Landmark Medical Center |
| Feb 13-15, 2001 | Newport Hospital |
| Feb 19-21, 2001 | St. Joseph Health Services of RI |
| Feb 22-23, 2001 | Butler Hospital |
| Feb 27-28, 2001 | Emma Pendleton Bradley Hospital |
| April 9 – 11, 2001 | Women & Infants Hospital of RI |
| April 30 – May 2, 2001 | Memorial Hospital of RI |
| May 7 – 11, 2001 | Emma Pendleton Bradley Hospital |
| June 5 – 7, 2001 | Eleanor Slater Hospital |
| July 9 – 13, 2001 | Rhode Island Hospital |
| August 6 – 8, 2001 | The Miriam Hospital |